III. Provisions of the Final Rule

In this final rule, we are adopting the provisions as set forth in the November 8, 1999 proposed rule with the following substantive revisions:

A. PART 431 -- STATE ORGANIZATION AND GENERAL ADMINISTRATION

We added a new §431.636 to provide for coordination of Medicaid with the State Children's Health Insurance Program. This section provides that the State must adopt procedures to facilitate the Medicaid application process for, and the enrollment of children for whom the Medicaid application and enrollment process has been initiated.

B. PART 433 -- STATE FISCAL ADMINISTRATION

We removed proposed paragaph §433.11(b)(3) regarding enhanced FMAP for disporportionate share hospital expenditures provided to certain children.

C. PART 435 -- ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

- We added a definition of optional targeted low-income child at §435.4.
- We revised §435.229 to refer to optional targeted low-income children as defined at §435.4.
- We revised §435.910(h)(3) to provide that a State may use the Medicaid identification number established by the State to

the same extent as an SSN is used for purposes described in paragraph (b)(3) of this section.

• At §435.1101 we replaced the term “applicable income level” with the term “presumptive income level.” The definition for this term remains the same.

• We revised the requirement at proposed paragraph §435.1102(b)(4) to provide that agencies that elect to provide services to children during a period of presumptive eligibility must allow determinations of presumptive eligibility to be made by qualified entities on a Statewide basis.

D. PART 436 -- ELIGIBILITY IN GUAM, PUERTO RICO, AND THE VIRGIN ISLANDS

In the proposed rule, we inadvertently omitted certain revisions to part 436. The following revisions parallel the changes made to part 435:

• We added a definition of optional targeted low-income children at §436.3.

• We added a new §436.229, regarding provision of Medicaid to optional targeted low-income children.

• We revised paragraph (a) of §436.1001, regarding FFP for administration.

• We added a new paragraph (c) to §436.1002, regarding FFP for services.

• We added a new subpart L, Option for Coverage of Special Groups.

E. PART 457 -- ALLOTMENTS AND GRANTS TO STATES

• We replaced the term “Children’s Health Insurance Program” with the term “State Children’s Health Insurance Program” throughout the regulation.

• We replaced the term “beneficiary” with the term “applicant” or “enrollee” throughout the regulation.

Subpart A -- Introduction; State Plans for State Child Health Insurance Programs and Outreach Strategies

§457.10

• We added definitions for the following terms: “applicant”, “cost sharing”, “enrollee”, “enrollment cap”, “health care services”, “health insurance coverage”, “health insurance issuer”, “health services initiatives”, “joint application”, “optional targeted low-income child”, and “premium assistance program”.

• For the following terms, we eliminated the cross reference and set forth the full text of the definition at §457.10: “contractor”, “emergency medical condition”, “emergency services”, “health benefits coverage”, “managed care entity”, “post-stabilization services”.

• We revised the definition of American Indian/Alaska Native (AI/AN) by removing the provision that descendants in the first

or second degree of members of Federally recognized tribes are considered AI/AN.

• We removed the definitions of “contractor”, “cost-effectiveness”, “employment with a public agency”, “grievance”, “legal obligation”, “post-stabilization services”, “premium assistance for employer sponsored group health plans”, and “State program integrity unit”.

§457.40

• We revised paragraph (c) to require that the State must identify, in the State plan or State plan amendment, b*y position or title,* the State officials who are responsible for program administration and financial oversight.

§457.60

• We revised proposed paragraph (a)(1) (now paragraph (a)) to provide that a State must amend its State plan whenever necessary to reflect changes in Federal law, regulations, policy interpretations, or court decisions *that affect provisions in the approved State plan*.

• We revised proposed paragraph (a)(2) (now paragraph (b)) to provide that a State must amend its State plan whenever necessary to reflect changes in State law, organization, policy, or operation of the program that affect the following program elements: eligibility, including enrollment caps and disenrollment policies; procedures to prevent substitution of

private coverage, including exemptions or exceptions to periods of uninsurance; the type of health benefits coverage offered; addition or deletion of specific categories of benefits offered under the plan; basic delivery system approach; cost-sharing; screen and enroll procedures, and other Medicaid coordination procedures, review procedures, and other comparable required program elements.

- We revised proposed paragraph (a)(3) (now paragraph (c)) to provide that a State must amend its State plan to reflect changes in the source of the State share of funding, except for changes in the type of non-health care related revenues used to generate general revenue.

§457.65

- We added a new paragraph (d) to set forth requirements for amendments relating to enrollment procedures.
- We redesignated proposed paragraphs (d) and (e) as paragraphs (e) and (f), respectively.
- We removed proposed paragraph (d)(2), as this provision has been incorporated into §457.60(c).
- We added a new paragraph (f)(2) to provide that an approved State plan continues in effect unless a State withdraws its plan in accordance with §457.170(b).

§457.70

• We removed proposed paragraph (c)(1)(vi), which provided that Medicaid expansion programs must meet the requirements of subpart H of this final rule.

§457.80

• We revised paragraph (c) to provide that the State plan must include a description of procedures the State uses to accomplish coordination of SCHIP with other public and private health insurance programs, sources of health benefits coverage for children, and relevant child health programs, such as title V, that provide health care services for low-income children.

§457.90

• We added a new paragraph (b)(3) to provide that outreach strategies may include application assistance, including opportunities to apply for child health assistance under the plan through community-based organizations and in combination with other benefits and services available to children.

§457.110

• We revised paragraph (a) to provide that the State must make linguistically appropriate information available to families.

• We revised paragraphs (a) and (b) to provide that the State must ensure that information is made available to applicants, and enrollees.

• We revised paragraph (b) to provide that States must have a mechanism in place to ensure that applicant and enrollees are provided specific information in a timely manner.

§457.120

• We added a new paragraph (c) to require that the State plan include a description of the method the State uses to ensure interaction of Indian Tribes and organizations on the implementation of procedures regarding provision of child health assistance to AI/AN children.

§457.125

• We revised paragraph (a) by removing language regarding consultation with Indian tribes, which has been incorporated into §457.120(c).

§457.140

• We revised the introductory text of this section to provide that a State plan or State plan amendment must include a 1-year budget.

§457.170

• We revised this section to provide more specific rules regarding withdrawal of proposed State plans or plan amendments and withdrawal of approved State plans.

§457.190

• We moved the provisions of §457.190 to new §457.203.

Subpart C -- State Plan Requirements: Eligibility, Screening, Applications and Enrollment

§457.301

- We removed our proposed definition of "employment with a public agency".
- We added a definition of the term “joint application”.

§457.305

- We revised paragraph (a) to provide that the State plan must include a description of the methodologies used by the State to calculate eligibility under the financial need standard.
- We added a new paragraph (b) to clarify that the State plan must describe the State’s policies governing enrollment and disenrollment, including enrollment caps, and processes for instituting waiting lists, deciding which children will be given priority for enrollment, and informing individuals of their status on a waiting list.

§457.310

- We revised the financial need standard for a targeted low-income child at paragraph (b)(1).
- We revised paragraph (b)(2)(ii) to provide that a child would not be considered covered under a group health plan if the child did not have reasonable *geographic* access to care under that plan.

• We revised paragraph (c)(1)(ii) to clarify our policy concerning contributions toward the cost of dependent coverage.

§457.320

• We revised paragraph (b)(3) to specifically prohibit discrimination on the basis of diagnosis.

• We revised paragraph (c) to permit States to accept self-declaration of citizenship, provided that the State has implemented effective, fair, and nondiscriminatory procedures for ensuring the integrity of their application process with respect to self-declaration of citizenship.

• We revised paragraph (a)(7) and added a new paragraph (d) to address eligibility standards related to residency.

• We revised paragraph (a)(10) and added a new paragraph (e) regarding duration of eligibility.

§457.340

• We removed proposed §457.340 and renamed this section, “Application for and enrollment in a separate child health program.” This section sets forth provisions regarding application assistance, notice of rights and responsibilities, timely determinations of eligibility, notice of decisions concerning eligibility, and effective date of eligibility.

§457.350

• We have revised this section for consistent use of the terms "found eligible" and "potentially eligible".

- We removed the provisions of proposed paragraph (b) regarding screening with joint applications.
- We redesignated proposed paragraph (c) as paragraph (b) and proposed paragraph (d) as paragraph (c)
- We revised paragraph (b) (proposed paragraph (c)) to require that a State must use screening procedures to identify, at a minimum, any applicant or enrollee who is potentially eligible for Medicaid under one of the poverty level related groups described in section 1902(l) of the Act, section 1931 of the Act, or a Medicaid demonstration project approved under section 1115 of the Act, applying whichever standard and corresponding methodology generally results in a higher income eligibility level for the age group of the child being screened.
- We added a new paragraph (d) to provide that if a State applies a resource test and a child has been determined potentially income eligible for Medicaid, the State must also screen for Medicaid eligibility by comparing the family's resources to the appropriate Medicaid standard.
- We have clarified the provisions of paragraph (e) (now paragraph (f)) regarding children found potentially eligible for Medicaid.
- We added new paragraphs (g) and (h) to specify requirements regarding informed application decisions and waiting lists, enrollment caps and closed enrollment.

§457.353

• We added a new section, “Evaluation of screening process and provisional enrollment.” This section sets forth requirements regarding monitoring and evaluations of the screen and enroll process, provisional enrollment during the screening process, and expenditures for coverage during a period of provisional enrollment.

§457.360

• We removed this section.

§457.365

• We removed the provisions of proposed §457.365, regarding grievances and appeals, and incorporated them into new subpart K.

§457.380 (proposed §457.970)

• We moved the provisions of proposed §457.970 to new §457.380.

• We removed the provision at proposed §457.970(d) that the State may terminate the eligibility of an applicant or beneficiary for “good cause.”

Subpart D -- Coverage and Benefits: General Provisions

§457.402

• We revised §457.402(a) to list surgical services separately at paragraph (a)(4).

• We moved the definitions of “emergency medical condition,” “emergency services,” and “health benefits coverage,” which were

set forth at proposed paragraphs (b), (c), and (e) respectively, to §457.10.

§457.410

• We revised paragraph (b)(1) to provide that the State must obtain coverage for well-baby and well-child care services *as defined by the State*.

• We revised paragraph (b)(2) to provide that the State must obtain coverage for *age-appropriate* immunizations.

§457.430

• We revised §457.430 by clarifying that benchmark-equivalent health benefits coverage must meet the requirements of §457.410(b) and by removing proposed paragraph (b)(4) regarding well-baby and well-child care and immunizations.

§457.440

• We revised paragraph (b)(2) to clarify that a State must submit an actuarial report when it amends its existing State-based coverage.

§457.450

• We revised paragraph (a) to provide that Secretary-approved coverage may include coverage that is the same as the coverage provided *to children* under the Medicaid State plan.

§457.490

• We revised §457.490(a) to provide that the State must describe the methods of delivery of child health assistance including the methods for assuring the delivery of the insurance products and the delivery of health care services covered by such products to the enrollees, including any variations.

§457.495

• We removed the provisions of proposed §457.495 regarding grievances and appeals and incorporated them into new subpart K.

• We moved the provisions of proposed §457.735 to §457.495, and renamed the section, “State assurance of access to care and procedures to assure quality and appropriateness of care”.

Subpart E -- State Plan Requirements: Beneficiary Financial Responsibilities

§457.500

• We added a new paragraph (a)(1) to add section 2101(a) of the Act to the statutory authority for this subpart.

• We revised paragraph (c) to remove the provision that, with respect to a mandatory cost-sharing waiver for AI/AN children, subpart E applies to a Medicaid expansion program.

§457.505

• We added a new paragraph (c) to §457.505 to provide that the State plan must include a description of the State’s disenrollment protections as required under §457.570.

§457.510

• We revised paragraph (d) to provide that when a State imposes premiums, enrollment fees, or similar fees, the State plan must describe the consequences for an enrollee or applicant who does not pay a charge and the disenrollment protections adopted by the State.

§457.515

• We revised paragraph (d) to provide that the State plan must describe the consequences for an enrollee who does not pay a charge and the disenrollment protections adopted by the State.

• We removed the statement from paragraph (e) the a methodology that primarily relies on a refund is not an acceptable methodology.

§457.520

• We revised §457.520(b) to provide that for the purposes of cost sharing, well-baby and well-child care services include routine examinations *as recommended by the AAP's "Guidelines for Health Supervision III", or as described in "Bright Futures: Guidelines for Health and Supervision of Infants, Children and Adolescents,"* Laboratory tests associated with the well-baby and well-child routine physical examinations, and immunizations as recommended and updated by ACIP.

§457.525

• We redesignated proposed paragraph (a)(4) as paragraph (a)(5) and revised this paragraph to provide that the public schedule must include information about consequences for an applicant or an enrollee who does not pay a charge including disenrollment protections.

• We added a new paragraph (a)(4) to provide that the public schedule must include information on mechanisms for making payments for required charges.

• We revised paragraph (b)(1) to require States to provide the public schedule to SCHIP enrollees at the time of reenrollment after a redetermination of eligibility, and when cost-sharing charges and cumulative cost-sharing maximums are revised.

§457.535

States may not impose premiums, deductibles, coinsurance, copayments or any other cost-sharing charges on children who are American Indians and Alaska Natives, as defined in §457.10.

§457.540

• We redesignated proposed paragraphs 457.550(a) and (b) as paragraphs 457.540(d) and (e).

• We redesignated proposed paragraph (e) as paragraph (f).

§457.545

• We removed the provisions of this section.

§457.550

• We eliminated this section and incorporated its contents into other sections of this subpart.

• We redesignated paragraphs (a) and (b) as §457.540(d) and (e).

• We redesignated paragraph (c) as § 457.555(e).

§457.555

• We revised §457.555(b) to indicate that cost sharing may not exceed 50 percent of the payment the State would make under the Medicaid fee-for-service system for the first day of care in the institution.

• We added a new paragraph (c) to provide that any copayment that the State imposes on services provided by an institution to treat an emergency medical condition may not exceed $5.00.

• We redesignated proposed paragraph (c) as paragraph (d).

• We removed proposed paragraph (d) regarding emergency room services provided outside and enrollee’s managed care network.

§457.560

• We reorganized this section for clarity.

§457.565

• We eliminated this section, as it has been incorporated into new subpart K.

§457.570

• We added the requirement, at paragraph (b), that the disenrollment process must afford the enrollee’s family the

opportunity to show that his or her income has declined prior to disenrollment for nonpayment of cost-sharing and charges, and in the event that such a showing indicates that the enrollee may have become eligible for Medicaid or for a lower level of cost sharing, the State must facilitate enrolling the child in Medicaid or adjust the child's cost-sharing category as appropriate.

• We added the requirement, at paragraph (c), that the State must provide the enrollee with an opportunity for an impartial review to address disenrollment from the program.

Subpart G -- Strategic Planning

§457.710

• We added a new paragraph (e) to provide that the State's strategic objectives, performance goals and performance measures must include a common core of national performance goals and measures consistent with the data collection, standard methodology, and verification requirements, as developed by the Secretary.

§457.735

• We moved the provisions of proposed §457.735 to §457.495.

§457.740

• We revised paragraph (a) to provide that Territories are exempt from the definition of “State” for purposes of quarterly reporting.

• We redesignated proposed paragraph (a)(2) as paragraph (a)(3) and added an new paragraph (a)(2) to provide that the quarterly reports must include data on a “point-in-time” enrollment count as of the last day of each quarter of the Federal fiscal year.

• We added a new paragraph (a)(3)(ii) to provide that the quarterly report must include data on the number of children enrolled in Medicaid by gender, race, and ethnicity.

§457.750

• We revised paragraph (b)(1) to provide that in the annual report, the State must include information related to a core set of national performance goals and measures as developed by the Secretary.

• We added a new paragraph (b)(7) to provide that the annual report must include data regarding the primary language of SCHIP enrollees.

• We added a new paragraph (b)(8) to provide that the annual report must describe the State’s current income standards and methodologies for its Medicaid expansion program and separate child health program as appropriate.

• We revised paragraph (c) to set forth requirements regarding the State's annual estimate of changes in the number of uninsured children in the State.

§457.760

• We removed this section.

Subpart H -- Substitution of Coverage

§457.810

• We added introductory text to paragraph (a).

• We revised paragraph (a)(1) to provide that an enrollee must not have had coverage under a group health plan for a period of at least 6 months prior to enrollment in a premium assistance program. A State may not require a minimum period without coverage under a group health plan that exceeds 12 months.

• We revised paragraph(a)(2) to specify the circumstances in which States may permit reasonable exceptions to the requirement for a minimum period without coverage under a group health plan.

• We removed proposed paragraph (a)(3), which specified that a newborn is not required to have a period without insurance as a condition of eligibility for payment for employer-sponsored group health coverage.

• We added a new paragraph (a)(3) to require that the requirement for a minimum period without coverage under a group health plan does not apply to a child who, within the previous 6

months, has received coverage under a group health plan through Medicaid under section 1906 of the Act.

• We added a new paragraph (a)(4) to specify that the Secretary may revise the 6-month waiting period requirement at her discretion.

• We revised paragraph (b) to provide that for health benefits coverage obtained through premium assistance for group health plans, the employee who is eligible for the coverage must apply for the full premium contribution available from the employer.

• We also removed paragraph (b)(1), which included the minimum 60 percent employer contribution requirement.

Subpart I -- Program Integrity

§457.902

• We added a definition of the term “actuarilly sound principles”.

• We moved the definition of “managed care entity” to §457.10.

• We eliminated the definitions of “contractor”, “grievance” and “State program integrity unit”.

§457.920

• We removed this section.

§457.940

• We revised paragraph (b)(2) to provide that a State must provide child health assistance in an effective and efficient manner by using payment rates based on public or private payment

rates for comparable services for comparable populations, consistent with principles of actuarial soundness.

§457.950

- We revised paragraph (a)(3) to provide that a State must ensure that its contract with an MCE provides access for the State, HCFA, and the HHS Office of the Inspector General to enrollee health claims data and payment data.
- We redesignated proposed paragraph (b)(2) as paragraph (b)(3).
- We added a new paragraph (b)(2) to provide that a State that makes payments to fee-for-service entities under a separate child health program must ensure that fee-for-service entities understand that payment and satisfaction of the claims will be from Federal and State funds, and that any false claims may be prosecuted under applicable Federal or State laws.

§457.955

- We added a new paragraph (b)(2) to provide that States must ensure that MCEs are prohibited from conducting any unsolicited personal contact with a potential enrollee by an employee or agent of a managed care entity for the purpose of influencing the individual to enroll with the entity.

§457.970

- We removed this section and incorporated its provisions into §457.380.

§457.975

- We removed this section.

§457.985

- We removed this section and incorporated its provisions into new subpart K.
- We added a new §457.985, Integrity of professional advice to enrollees.

§457.990

- We removed this section and incorporated its provisions into new subpart K.

§457.995

- We removed this section and incorporated its provisions into new subpart K.

Subpart J -- Allowable Waivers: General Provisions

§457.1000

- We revised paragraph (c) to provide that this subpart applies to a Medicaid expansion program when the State claims administrative costs under title XXI and seeks a waiver of limitations on such claims for use of a community-based health delivery system. This subpart does not apply to demonstrations requested under section 1115 of the Act.

§457.1003

• We added a new §457.1003 to provide that HCFA will review the waivers in this subpart as State plan amendments under the same timeframes for State plan amendments specified in subpart A.

§457.1005

• We revised §457.1005(c) to provide that an approved waiver for cost-effective coverage through a community-based health delivery system remains in effect for no more than 3 years.

§457.1015

• We removed the requirement at paragraph (b)(2) regarding demonstrating cost-effectiveness through comparison with a child-only health benefits package.

Subpart K -- Applicant and Enrollee Protections

• We relocated certain provisions involving applicant and enrollee protections to this new subpart K, “Applicant and Enrollee Protections.” Specifically, we moved to this subpart proposed §457.985, which set forth requirements relating to grievances and appeals, and proposed §457.990, which set forth requirements for privacy protections.

• We added the following sections in response to public comment: §457.1140, Core elements of review; §457.1170, Continuation of Benefits; and §457.1190, Premium assistance for group health plans.

• The following table shows the disposition of the sections set forth in the proposed rule that have been incorporated into subpart K.

Proposed Regulations	Final Regulations

Definitions -- Contractor	
457.902.....	Deleted
Definitions -- Grievance	
457.902.....	Deleted
Denial, Suspension, or Termination of Eligibility	Revised 457.1130(a)
457.365.....	Revised 457.1130(b)
Reduction or Denial of Services	Revised 457.1130(a)
457.495.....	Revised 457.1180
Disenrollment for Failure to Pay Cost Sharing	Revised 457.1130(a) and 457.1180
457.565.....	Revised 457.1130(a) and 457.1180 Revised 457.1130(b) and 457.1180
Enrollees Rights to File Grievances and Appeals	Revised 457.1120, 1150(b), and 457.1160 Deleted
457.985(a).....	Deleted Deleted Deleted
457.985(a)(1).....	Deleted Revised 457.985, Cross Reference 457.110(b)(5)
457.985(a)(2).....	Revised 457.985, Cross Reference 457.110(b)(5)
457.985(a)(3).....	Revised 457.1110(b) Revised 457.1110
457.985(b).....	Revised 457.1110(a) and (d) Revised 457.1110(a) and (d)
457.985(c).....	Revised 457.1110(a) Revised 457.1110(a)
457.985(c)(1).....	Revised 457.1110(c) and (e) Revised 457.1110(a)
457.985(c)(2).....	Deleted Deleted
457.985(d).....	Deleted
457.985(e).....	Revised 457.1110(e) Revised 457.1120 and 457. 1180, Cross Reference
457.985(e)(1).....	457.110(b)(6) Revised 457.1130(a)
457.985(e)(2).....	Revised 457.1130(b)
Privacy Protections	Revised 457.1130(a)(3) Revised 457.1160
457.990(a).....	

F. Technical Corrections

In this final rule we are making the following technical corrections to subpart B, General Administration, and subpart F, Payments to States, of part 457. These subparts were published in final on May 24, 2000 (65 FR 33616).

Subpart B -- General Administration -- Reviews and Audits; Withholding for Failure to Comply; Deferral and Disallowance of Claims; Reduction of Federal Medical Payments

- We moved the provisions of proposed §457.190 regarding administrative and judicial review to new §457.203, as we believe these provisions are more appropriately located in subpart B.
- We revised §457.204(d)(2) to clarify the meaning of the term “corrective action.”
- We revised §457.208(a) to cross refer to the provisions of new §457.203.
- We removed §457.234, State plan requirements, as these provisions duplicate §457.50.

Subpart F -- Payments to States

- We removed §457.624, Limitations of certain payments for certain expenditures, as paragraphs (a) and (b) of this section duplicate the provisions of §§457.475 and 457.1010, respectively.

IV. Regulatory Impact Analysis

A. Impact Statement

Section 804(2) of title 5, United States Code (as added by section 251 of Public Law 104-121), specifies that a "major rule" is any rule that the Office of Management and Budget finds is likely to result in--

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment productivity, innovation, or on the ability of United States based enterprises to compete with foreign based enterprises in domestic and export markets.

This final rule does not establish the SCHIP allotment amounts. However, it provides for the implementation and administration of the SCHIP program, and as such, is an economically significant, major rule.

We have examined the impacts of this final rule as required by Executive Order 12866, the Unfunded Mandate Reform Act of 1995 (Pub. L. 104-4), and the Regulatory Flexibility Act (RFA) (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory

alternatives and, when regulations are necessary, to select regulatory approaches that maximize net benefits (including potential economic environments, public health and safety, other advantages, distributive impacts, and equity).

The Unfunded Mandates Reform Act of 1995 requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation)in any one year. Because participation in the SCHIP program on the part of States is voluntary, any payments and expenditures States make or incur on behalf of the program that are not reimbursed by the Federal government are made voluntarily. These regulations implement narrowly defined statutory language and would not create an unfunded mandate on States, tribal or local governments.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any final rule that may have a significant impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain rural counties adjacent to urban areas, for purposes of section 1102(b) of the

Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

In addition, for purposes of the RFA, we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, non-profit organizations, and governmental agencies. Most hospitals and other providers and suppliers are small entities, either by non-profit status or by having revenues of $5 million or less annually. Individuals and State agencies are not included in the definition of small entity. As discussed in detail below, this final rule will have a beneficial impact, if any, on health care providers.

Therefore, we are not preparing an analysis for section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant impact on a substantial number of small entities or on the operations of a substantial number of small rural hospitals.

B. Cost Benefit Analysis

This analysis addresses a wide range of costs and benefits of this rule. Whenever possible, we express impact quantitatively. In cases where quantitative approaches are not feasible, we present our best examination of determinable costs,

benefits, and associated issues. This final regulation would implement all programmatic provisions of the State Children's Health Insurance Program (SCHIP) including provisions regarding State plan requirements, benefits, eligibility, and program integrity, which are specified in title XXI of the Act. This final regulation would have a beneficial impact in that it would allow States to expand the provision of health benefits coverage to uninsured, low-income children who previously had limited access to health care.

SCHIP is the largest single expansion of health insurance coverage for children since the creation of Medicaid in 1965. SCHIP was designed to reach children from working families with incomes too high to qualify for Medicaid, but too low to afford private health insurance. As discussed in detail below, this initiative set aside $40 billion over ten years for States to provide new health coverage for millions of children. To date, plans prepared by all 50 States, 5 U.S. territories, and the District of Columbia have been approved. We estimate that States enrolled at least 3 million children in fiscal year 2000. The implementation of SCHIP has significantly reduced the number of uninsured children nationwide. Previously uninsured children now have access to a range of health care services including well baby and well child care, immunizations, and emergency services. In addition to the obvious benefit of providing access to health

care coverage for millions of children, as discussed in detail below, SCHIP will also have a beneficial impact on the private sector.

1. Disbursement of Federal Funds

Budget authority for title XXI is specified in section 2104(a) of the Act with additional funding authorized in Pub. L. 105-100. The total national amount of Federal funding available for allotment to the 50 States, the District of Columbia, and the Commonwealths and Territories for the life of SCHIP, is established as follows:

TOTAL AMOUNT OF ALLOTMENTS

Fiscal Year	Amount
1998	$4,295,000,000
1999	4,275,000,000
2000	4,275,000,000
2001	4,275,000,000
2002	3,150,000,000
2003	3,150,000,000
2004	3,150,000,000
2005	4,050,000,000
2006	4,050,000,000
2007	5,000,000,000

Under Public Law 105-277, an additional $32 million was appropriated for allotment only to the Commonwealths and Territories, and only for FY 1999. In addition, we note that there was an additional allocation of $20 million in FY 1998, which increases the FY 1998 total allotment amount to $4.295

billion. Also, for each of the first five years, $60 million of the allotment must be used for the special diabetes programs.

Section 702 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106-113, BBRA) appropriated an additional $249 million for Territories. In addition, section 703(c) of the BBRA requires that the Secretary conduct an independent evaluation of 10 States with approved child health plans and appropriates $10 million for FY 2000 for this purposes. The additional allotments for Territories are established as follows:

INCREASED ALLOTMENTS FOR TERRITORIES

Fiscal Year	Amount
2000	$34,200,000
2001	34,200,000
2002	25,200,000
2003	25,200,000
2004	25,200,000
2005	32,400,000
2006	32,400,000
2007	40,000,000

We note that the Federal spending levels for the SCHIP program are based entirely on the spending and allocation formulas contained in the statute. The Secretary has no discretion over these spending levels and initial allotments of

funds allocated to States. Both direct program and administrative costs are covered by the allotments.

2. Impact on States

SCHIP is a State-Federal program under which funds go directly to States, which have great flexibility in designing their programs. Specifically, within broad Federal guidelines, each State determines the design of its program, eligible groups, benefit packages, payment levels for coverage and administrative and operating procedures. As such, it is difficult to quantify the economic impact on States beyond the obvious benefit of additional funding provided at an “enhanced” matching rate as compared to the matching rates for the Medicaid program. As stated above, the total Federal payments available to States are specified in the statute and are allocated according to a statutory formula based on the number of uninsured, low-income children for each State, and a geographic adjustment factor. For qualifying expenditures, States will receive an enhanced Federal matching rate equal to its current FMAP increased by 30 percent of the difference between its regular matching rate and 100 percent, except that the enhanced match cannot exceed 85 percent.

The following chart depicts estimated outlays for the SCHIP program. These estimates differ from the allotments referred to above in that the allotments allow the money to be spent over a period of three years.

Fiscal Year Outlays in $Billions					
	1999	2000	2001	2002	2003
Federal Share	0.6	1.3	1.9	2.5	3.0
State Share	0.2	0.6	0.8	1.1	1.3
Total	0.8	1.9	2.7	3.6	4.3

Note: These estimates are based on State and Federal budget projections and have been included in the President's FY 2001 budget. Outlay estimates do not include costs for Medicaid expansion programs but only for separate child health programs.

Because the final rule largely confirms the provisions in the proposed rule, which were based on previously released guidance, most States' programs are already in compliance with these Federal requirements. In addition, this final rule includes a balance of provisions that provide additional flexibility for States with further clarification of the intent of the statute. Therefore, coupled with the fact that States are working with a limited amount of funds, we do not anticipate that the publication of this rule will have a significant or unexpected impact on States.

3. Impact on the Private Sector

We note that due to the flexibility that States have in designing and implementing their SCHIP programs it is not possible to determine the impact on individual providers groups

of providers, insurers, health plans, or employers. However, we anticipate that the SCHIP program will benefit the private sector in a number of ways. The program may have a positive impact on a number of small entities given that SCHIP funding will filter down to health care providers and health plans that cover the SCHIP population. Health plans that provide insurance coverage under the SCHIP program will benefit to the extent that children are generally a lower-risk population. That is, children tend to use fewer high-cost health care services than older segments of the population. Thus, by providing health insurance coverage for preventive care such as well-baby and well-child care and immunizations, SCHIP may benefit health insurers by reducing the need to provide more costly health care services for serious illnesses. Additionally, because SCHIP provides health insurance coverage to children who were previously uninsured, health care providers will no longer have to absorb the cost of uncompensated care for these children. The private sector may also benefit from SCHIP to the extent that children and families with health insurance coverage are more likely to use health care services. Thus, health care providers are likely to experience an increase in demand for their services. Small businesses that are unable to afford private health insurance for their employees will benefit to the extent that the employees, or their children qualify for SCHIP. However, because States have largely been

operating their SCHIP programs in accordance with the proposed rule since the beginning of their programs, we do not anticipate the final rule will have a significant impact on the private sector, with the exception of the potential for additional program expansions.

4. Impact on Beneficiaries

The main goal of SCHIP is to provide health insurance coverage for children in families that are not eligible for Medicaid, but do not earn enough to afford private health insurance. SCHIP will allow a large number of children who were previously uninsured to have access to health insurance and the opportunity to receive health care services on a regular basis.

Supart E of this final rule sets forth provisions regarding the costs that beneficiaries may incur (cost sharing) under SCHIP. In accordance with the statute, we set forth provisions concerning general cost sharing protection for lower income children and American Indians/Alaska Natives, cost sharing for children from families with certain income levels, and cumulative cost-sharing maximums. Section 457.555 sets forth maximum allowable cost sharing charges on targeted low-income children in families with income from 101 to 150 percent of the FPL. This section specifies maximum copayment amounts that may be imposed under fee-for-service delivery systems and managed care organizations. Additionally, regarding cumulative cost sharing

maximums, §457.560 provides that cost sharing for children with family income above 150 percent of the Federal poverty level may not exceed 5 percent of total family income for the year. For children with family income at or below 150 percent of the Federal poverty level, cost sharing may not exceed 2.5 percent of total family income for the year.

We note that due to State flexibility in establishing cost-sharing amounts below the maximums and differing utilization patterns among beneficiaries, it is difficult to quantify the amount of cost sharing that families incur to participate in SCHIP. However, in light of the number of children enrolled in SCHIP, we believe that for most beneficiaries, the benefit of access to health insurance coverage outweighs the costs associated with participation in the program.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

We received the following comment on the impact analysis:

Comment: Several commenters believe that the regulation is administratively burdensome. Specifically, commenters asserted that the administrative funding for SCHIP is insufficient to effectively operate a State plan under the proposed regulations. The proposed rule fails to adequately acknowledge that State budgets for outreach and administrative activities are limited to

10 percent of total expenditures. Commenters believe this method of computing the administrative cap places States in a difficult position because in order to increase enrollment (and consequently the State's total expenditures), States must incur expenditures for outreach. Commenters recommended that we exclude outreach expenditures from the 10 percent cap.

Commenters also noted that the proposed regulations create additional administrative burdens that do not improve services and may force States to revise programs at additional costs to States. They indicated that for Medicaid expansion programs, Federally required systems changes are matched at 90 percent with no cap. However, the proposed regulations do not offer a similar provision for separate child health programs required to make changes to existing systems. Additionally, separate child health programs are required to absorb these costs within the limited 10 percent administrative cap.

Commenters strongly recommended that we carefully consider the administrative feasibility and the cost of the proposed regulations for SCHIP eligibles and their families, States and MCEs. Commenters argued that the burden of high administrative costs will be particularly difficult for health plans to bear because per enrollee revenues are comparatively small under SCHIP. The commenters suggested that we evaluate carefully the costs and benefits of administrative requirements to avoid

threatening the economic viability of SCHIP programs. The participation of private health plans can offer significant advantages in providing attractive plans for beneficiaries, organizing provider networks, controlling costs and delivering innovations from the employer-based market. However, the low cap on administrative expenses has served to deter some private plans from participating in SCHIP programs. Some private health plans have found it difficult to forecast the financial risk associated with covering children under this program and are concerned that they cannot provide for adequate reserves under the cap.

Response: Under section 2105(c)(2)(A) of the Act, States may receive funds at the enhanced FMAP for administrative expenditures, outreach, health services initiatives, and certain other child health assistance, only up to a "10 Percent Limit." The "10 Percent Limit" found in the statute specifies that the "total computable" amount of these expenditures (the combined total State and Federal share of benefit and administrative expenditures) for which FFP may be claimed cannot exceed 10 percent of the sum of the total computable expenditures made under section 2105(a) of the Act and the total computable expenditures based on the enhanced match made under sections 1905(u)(2) and (u)(3) of the Act.

It is important to note that States may mitigate the effect of little or no program expenditures on the calculation of the 10

percent limit in one fiscal year by delaying the claiming of administrative expenditures until a subsequent fiscal year. In that case, the delayed administrative expenditures could be applied against the subsequent year's 10 percent limit, which may be calculated using presumably higher program expenditures. This should prove helpful to States now that their programs are up and running and the original start up costs are diminishing. In addition, as States gain more experience operating their programs, administrative costs should fall below the 10 percent cap on administrative expenditures.

In response to the comment that some health plans have found it difficult to foresee the risk associated with covering children under this program, we have no requirement for plan administrative costs. These costs are subject to negotiations between the individual health plan and the State in a risk based capitated arrangement.

V. Federalism

Under Executive Order 13132, we are required to adhere to certain criteria regarding Federalism in developing regulations. Title XXI authorizes grants to States that initiate or expand health insurance programs for low-income, uninsured children. A State Children's Health Insurance Program (SCHIP) under title XXI is jointly financed by the Federal and State governments and is administered by the States. Within broad Federal guidelines,

each State determines the design of its program, eligible groups, benefit packages, payment levels for coverage and administrative and operating procedures. States have great flexibility in designing programs to best meet the needs of their beneficiaries. HCFA works closely with the States during the State plan and State plan amendment approval process to ensure that we reach a mutually agreeable decision.

Federal payments under title XXI to States are based on State expenditures under approved plans that could be effective on or after October 1, 1997. The short time frame between the enactment of the Balanced Budget Act (BBA) (August 5, 1997) and the availability of the funding for States required the Department to begin reviewing SCHIP plans submitted by States and Territories at the same time as it was issuing guidance to States on how to operate the SCHIP programs. The Department worked closely with States to disseminate as much information as possible, as quickly as possible, so States could begin to implement their new programs expeditiously.

To be more specific, the Department began issuing guidance to States within one month of enactment of the BBA. We provided information on each State's allotment through two **Federal Register** notices published on September 12, 1997 (62 FR 48098) and February 8, 1999 (64 FR 6102). We developed a model application template to assist State's in applying for title XXI

funds. We provided over 100 answers to frequently asked questions. We issued policy guidance through a series of 23 letters to State health officials. All of this information is currently available on our website located on the Internet at http://www.hcfa.gov. We have also provided technical assistance to all States in development of SCHIP applications.

On November 8, 1999 we published in the **Federal Register** a proposed rule that set forth all programmatic provisions for SCHIP (64 FR 60882). We received 109 timely comments on the proposed rule. Interested parties that commented included States, enrollee advocate organizations, individuals, and provider organizations. The comments received varied widely and were often very detailed. We received a significant number of comments on the following areas: State plan issues, such as when an amendment to an existing plan is needed; the exemption to cost sharing for American Indian/Alaska Native children; eligibility "screen and enroll" requirements; Medicaid coordination issues; eligibility simplification options such as presumptive eligibility; the definition of a targeted low-income child; substitution of private coverage; data collection on race, ethnicity, gender and primary language; grievance and appeal procedures; and premium assistance for employer-sponsored coverage. In this final rule we provide detailed responses to all issues raised by the commenters.

The final programmatic regulation incorporates much of the guidance that already has been issued to States. As the final regulation builds upon previously released guidance, most of the regulation represents policies that have been in operation for some time and are a result of the consultation process that is required as part of the implementation of SCHIP; specifically, the State plan approval process. In developing the interpretative policies set forth in this final rule, we also listened to the concerns of States through processes other than the State plan process as well, by attending conferences and meeting with various groups representing State and public interests. We consulted with State and local officials in the course of the design and review stages of State proposals, and many of the policies found in the proposed and this final rule are a direct result of these discussions and negotiations with the States. To the extent consistent with the objectives of the statute, to obtain substantial health care coverage for uninsured low-income children in an effective an efficient manner, we have endeavored to preserve State options in implementing their programs. As we continue to implement the program, we have identified a number of areas in which we further elaborate on previous guidance or implement new policies. A summary of key issues is set forth at section II.A.1 of the preamble to this final rule.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comments on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirement discussed below. The following sections of this document contain information collection requirements:

Section 457.50 -- State plan.

In summary, §457.50 requires a State to submit a child health plan to HCFA for approval. The child health plan is a comprehensive written statement submitted by the State describing the purpose, nature, and scope of its Child Health Insurance Program and giving assurance that it will be administered in conformity with the specific requirements of title XIX (as appropriate), title XXI, and the regulations in this chapter. The State plan contains all information necessary for HCFA to determine whether the plan can be approved to serve as a basis for Federal financial participation in the State program.

The burden associated with this requirement is the time and effort for a State to prepare and submit its child health plan to HCFA for approval. These collection requirements are currently approved by OMB under OMB# 0938-0707.

Section 457.60 -- Amendments.

In summary, §457.60 requires a State to submit to HCFA for approval an amendment to its approved State plan, whenever necessary, to reflect any changes in; 1) Federal law, regulations, policy interpretations, or court decisions, 2) State law, organization, policy or operation of the program, or 3) the source of the State share of funding.

The burden associated with this requirement is the time and effort for a State to prepare and submit any necessary amendments to its State plan to HCFA for approval. Based upon HCFA's

previous experiences with State plan amendments we estimate that on average, it will take a State 80 hours to complete and submit an amendment. We estimate that 10 States/territories will submit an amendment on an annual basis for a total burden of 800 hours.

Section 457.70 -- Program options.

In summary, §457.70 requires a State that elects to obtain health benefits coverage through its Medicaid plan to submit an amendment to the State's Medicaid State plan as appropriate, demonstrating that it meets specified requirements in subparts A, B, C, F, G and J of part 457 and the applicable Medicaid regulations.

The burden associated with this requirement is the time and effort for a State to prepare and submit the necessary amendment to its Medicaid State plan to HCFA for approval. Based upon HCFA's previous experiences with State Plan amendments we estimate that on average, it will take a State 2 hours to complete and submit an amendment for HCFA approval. We estimate that 28 States/territories will submit an amendment for a total one-time burden of 56 hours.

Section 457.350 -- Eligibility screening.

In summary, §457.350 requires a State that chooses to screen for Medicaid eligibility under the poverty level related groups described in 1902(l)of the Act, to provide written notification to the family if the child is found not to be Medicaid eligible.

The burden associated with this requirement is the time and effort for a State to prepare and provide written notification to the family if the child is found not to be Medicaid eligible. The average burden upon the State to prepare the notice is a one time burden estimated to be 10 hours and that it will take 3 minutes for the State to provide and the family to read the information. We estimate that on average, that each State will be required to provide 1 million notices on an annual basis for a total annual burden of 50,000 hours, per State. Therefore, the total estimated burden is calculated to be 2,700,000 hours on an annual basis.

Section 457.360 -- Facilitating Medicaid enrollment.

In summary §457.360(c) requires a State to provide full and complete information, in writing to the family (that meets the requirements of (c)(1) through (c)(2) of this section), to ensure that a decision by the family not to apply for Medicaid or not to complete the Medicaid application process represents an informed decision.

The burden associated with this requirement is the time and effort for a State to prepare and provide written notice to the family to ensure that a decision by the family not to apply for Medicaid or not to complete the Medicaid application process represents an informed decision. The average burden upon the State to disseminate a standard notice to the family is estimated

to be 3 minutes. We estimate that on average, each State will be required to provide 1 million notices on an annual basis for a total annual burden of 50,000 hours, per State. Therefore, the total estimated burden is calculated to be 2,700,000 hours on an annual basis.

Section 457.361 -- Application for and enrollment in CHIP.

In summary, §457.361(b) requires a State to inform applicants, at the time of application, in writing and orally if appropriate, about the eligibility requirements and their rights under the program.

The burden associated with this requirement is the time and effort for a State to inform each applicant in writing and orally if appropriate, about the eligibility requirements and their rights and obligations under the program. We estimate the average burden upon the State to disseminate a standard notice to the family is estimated to be 3 minutes. We estimate that on average, each State will be required to provide 1 million notices on an annual basis for a total annual burden of 50,000 hours, per State. Therefore, the total estimated burden is calculated to be 2,700,000 hours on an annual basis.

In summary, §457.361(c) requires a State to send each applicant a written notice of the agency’s decision on the application and, if eligibility is denied or terminated in accordance with §457.1170(b)(that is, the specific reason or

reasons for the action and an explanation of the right to request a hearing within a reasonable time).

The burden associated with this requirement is the time and effort for a State to prepare and provide written notice to each applicant of the agency's decision on the application, and if eligibility is denied or terminated, the specific reason or reasons for the action and an explanation of the right to request a hearing within a reasonable time. We estimate that on average, it will take each State 3 minutes to prepare each notice and that each State will be required to provide 1 million notices on an annual basis for a total annual burden of 50,000 hours, per State. Therefore, the total estimated burden is calculated to be 2,700,000 hours on an annual basis.

Section 457.431 -- Actuarial report for benchmark-equivalent coverage.

In summary, §457.431 requires a State that wants to obtain approval for benchmark-equivalent benefits coverage described under §457.430 to submit to HCFA an actuarial report that: 1) compares the actuarial value of coverage of the benchmark package to the State-designed benchmark-equivalent benefit package; 2) demonstrates through an actuarial analysis of the benchmark-equivalent package that coverage requirements under §457.430 are met; and 3) meets the requirements of §457.431(b).

The burden associated with this requirement is the time and effort for a State that wants to obtain approval for benchmark-equivalent benefits coverage described under §457.430 to prepare and submit its actuarial report to HCFA for approval. We estimate that, on average, it will take a State 40 hours to prepare and submit a report for HCFA approval. We estimate that 6 States/territories will submit a plan for a total burden of 240 hours.

Section 457.440 -- Existing State-Based Comprehensive Coverage.

Under paragraph (b) of this section, a State may modify an existing comprehensive State-based coverage program described in paragraph (a) of the section if, among other items, the State submits an actuarial report when it amends its existing coverage.

The burden associated with this requirement is the time and effort for a State needs to prepare an actuarial report. There are only three States that would have this option; we do not anticipate that more than one of them would modify its program in a given year. It would take that State an average of 40 hours to prepare the report.

Section 457.525 -- Public schedule.

In summary, §457.525(b) requires a State to make the public schedule required under paragraph (a) available to:

(1) SCHIP enrollees, at the time of enrollment and reenrollment after a redetermination of eligibility, and when

cost-sharing charges and cumulative cost-sharing maximums are revised.

(2) SCHIP applicants, at the time of application.

(3) All SCHIP participating providers.

(4) The general public.

The burden associated with this requirement is the time and effort for a State to prepare and make available its public schedule available to these four groups. We estimate that on average, it will take each State/Territory 120 minutes to prepare its public schedule and 3 minutes to disseminate no more than 20,000 copies of its schedule on an annual basis for a total annual burden of 1000 hours, per State/Territory. Therefore, the total estimated burden is calculated to be 54,000 hours on an annual basis.

Section 457.570 Disenrollment protections.

Under paragraph (a) of this section, a State must give enrollees reasonable written notice of and an opportunity to pay past due premiums, copayments, coinsurance, deductibles or similar fees prior to disenrollment.

The burden associated with this requirement is the time and effort for a State to prepare a standardized notice and to fill out and give the enrollees the notice. We estimate that it will take each State four hours to create a notice, for a national burden of 216 hours. We anticipate that it will take no longer

than 10 minutes per enrollee to fill out the notice and give it to the enrollee; we estimate that approximately five per cent of enrollees will be given notices. If there are 2.6 million children enrolled, as projected, the burden nationally will be 21,700 hours of burden [(2.6 million X 5 percent X 10 minutes) ÷ 60].

Section 457.740 -- State expenditure and statistical reports.

In summary, §457.740 requires a State to submit a report to the Secretary that contains quarterly program expenditures and statistical data, no later than 30 days after the end of each quarter of the federal fiscal year. The burden associated with this requirement is the time and effort for a State to prepare and submit its report to the Secretary. These collection requirements are currently approved by under OMB approval number OMB# 0938-0731, with a current expiration date of 1/31/2002.

In addition §457.740 requires a State to submit an annual report, thirty days after the end of the Federal fiscal year, of an unduplicated count for the Federal fiscal year of children who are enrolled in the title XIX Medicaid program, and the separate child health and Medicaid-expansion programs, as appropriate, by age, service delivery, and income categories described in paragraphs (a) and (b) of this section.

The burden associated with this requirement is the time and effort for a State to prepare and submit its annual report to the

Secretary. We estimate that on average, it will take a State 40 hours to complete and submit their report. We estimate that 54 States/territories will submit a plan for a total burden of 2160 hours.

Section 457.750 -- Annual report.

In summary, §457.750 requires a State to submit a report to the Secretary by January 1 following the end of each federal fiscal year, on the results of the State's assessment of operation of the State child health plan.

The burden associated with this requirement is the time and effort for a State to prepare and submit its annual report on the results of the State's assessment of operation of the State child health plan. We estimate that on average, it will take a State 40 hours to complete and submit their report. We estimate that 54 States/territories will submit a plan for a total burden of 2160 hours.

Section 457.810 -- Premium assistance for employer-sponsored group health plans: Required protections against substitution.

In summary, §457.810(d) requires a State that uses title XXI funds to provide premium subsidies under employer-sponsored group health plans to collect information to evaluate the amount of substitution that occurs as a result of the subsidies and the effect of subsidies on access to coverage.

The burden associated with this requirement is the time and effort for a State to collect the necessary data to evaluate the amount of substitution that occurs as a result of the subsidies and the effect of subsidies on access to coverage. We estimate that on average, it will take a State 20 hours to collect the necessary data for their evaluation. We estimate that 54 States/territories will submit a plan for a total burden of 1,080 hours.

Section 457.940 -- Procurement standards.

Under paragraph (a), a State must submit to HCFA a written assurance that title XXI services will be provided in an effective and efficient manner. The burden associated with this requirement is the time and effort for a State to write this assurance. We believe that the time involved will be minimal and assign one hour per State for this requirement.

Section 457.950 -- Contract and payment requirements including certification of payment-related information.

This section, in paragraph (b), requires a State that makes payments to fee-for-service entities under a separate child health program to --

(1) Establish procedures to certify and attest that information on claim forms is truthful, accurate, and complete.

(2) Ensure that fee-for-service entities understand that

payment and satisfaction of the claims will be from federal and State funds, and that any false claims may be prosecuted under applicable federal or State laws.

(3) Require, as a condition of participation, that fee-for-service entities provide the State, HCFA and/or the HHS Office of the Inspector General with access to enrollee health claims data, claims payment data and related records.

The burden associated with this requirement is the time and effort for a State to establish procedures. It is also the time and effort required for a fee-for-service entity to certify and attest that information on claim forms is truthful, accurate, and complete and to provide access to the required data to the State, HCFA and/or the HHS Office of the Inspector General. Depending on the situation, we estimate that the time required to complete such a certification would be 8 hours per certification, per year. Therefore, 8 hours X 51 States and Territories for a total burden of 408 hours per year.

Section 457.965 -- Documentation.

In summary, §457.965 requires a State to include in each applicant’s record facts to support the State’s determination of the applicant’s eligibility for CHIP. While this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA as defined in 5 CFR

1320(b)(3), because this requirement would be imposed in the absence of a Federal requirement.

Section 457.985 -- Integrity of professional advice to enrollees.

Under this section, the State must guarantee, in all contracts for coverage and services, beneficiary access to information, in accordance with §§422.208 and 422.210(a) and (b), related to limitations on physician incentives or compensation arrangements that have the effect of reducing or limiting services and information requirements respectively.

The burden associated with this requirement is the time and effort for a State to include this guarantee in its contract(s) and for its contractor(s) to give beneficiaries access. We estimate that it will take a token hour for each State to comply with this requirement. We estimate that it will take each contractor 1 hour to include this assurance in its contracts, however the number of contractors that will be affected cannot be known, as States have flexibility to use contractors as they deem appropriate.

Section 457.1005 -- Waiver for cost-effective coverage through a community-based health delivery system.

In summary, §457.1005 requires a State requesting a waiver for cost-effective coverage through a community-based health delivery system, to submit documentation to HCFA that

demonstrates that they meet the requirements of §457.1005(b)(1) and (b)(2).

The burden associated with this requirement is the time and effort for a State that wants to obtain a waiver to prepare and submit the necessary documentation to HCFA that demonstrates that they meet the requirements of §457.1005.

We estimate that on average, it will take a State 24 hours to prepare and submit a waiver request for HCFA approval. We estimate that 10 States/territories will submit a request for a total burden of 240 hours.

Section 457.1015 -- Cost effectiveness.

In summary, §457.1015 requires a State to report to HCFA in its annual report the amount it spent on family coverage and the number of children it covered. While this requirement is subject to the PRA, the burden associate with this requirement is captured in §457.750 (Annual report).

Section 457.1180 -- Notice

Under this section, a State must provide enrollees and applicants timely written notice of any determinations required to be subject to review under §457.1130, a notice that includes the reasons for the determination; an explanation of applicable rights to review of that determination, the standard and expedited time frames for review, and the manner in which a

review can be requested; and the circumstances under which benefits may continue pending review.

The burden associated with this requirement is the time and effort for a State to prepare and give out the notice. We estimate that it will take each State four hours (216 hours nationally) to develop a standardized form into which enrollee-specific information may be inserted and a half hour per enrollee to prepare and give out the notice. We estimate that approximately 10 percent of enrollees will receive a notice under this provision, or 130,000 hours nationally [(2.6 million X 30 minutes X 10 percent) ÷ 60 minutes].

We have submitted a copy of this final rule to OMB for its review of the information collection requirements in **§§** 457.50, 457.60, 457.70, 457.350, 457.360, 457.361, 457.431, 457.440, 457.525, 457.740, 457.750, 457.760, 457.810, 457.940, 457.965, 457.985, 457.1005, 457.1015, and 457.1140. These requirements are not effective until they have been approved by OMB.

If you have any comments on any of these information collection and record keeping requirements, please mail the original and 3 copies directly to the following:

Health Care Financing Administration,

Office of Information Services,

Standards and Security Group,

Division of HCFA Enterprise Standards,

Room N2-14-26, 7500 Security Boulevard,

Baltimore, MD 21244-1850.

Attn: Julie Brown HCFA-2006-P.

And,

Office of Information and Regulatory Affairs,

Office of Management and Budget,

Room 10235, New Executive Office Building,

Washington, DC 20503,

Attn: Brenda Aguilar, HCFA Medicaid Desk Officer.